

Substance: 1,3,4-Thiadiazole, 2,5-bis(tert-nonyldithio)

Summary prepared by: Petroleum Additives Panel
Health & Environmental Research Task Group

1. General Information

1.1 Physico-chemical Data

1.1.1 Octanol Water Partition Coefficient

Robust Summary 7-LogKow-1

CAS No.	89347-09-1										
Test Substance Name	1,3,4-thiadiazole, 2,5-bis(tert-nonyldithio);										
Purity	80 %–90% 1,3,4-thiadiazole, 2,5-bis(tert-nonyldithio) 10%-20% 2-Mercapto-5-tert-nonyldithio-1,3,4-thiadiazole.										
Test Type	Octanol/Water Partition Coefficient										
Method/Guideline	OECD Test Guideline 107										
GLP (Y/N)	Yes										
Year	1990										
Test Substance Stock Solution	A test substance stock solution was prepared as a mixture of radiolabeled and unlabeled test material. This mixture was diluted in 10 mL of methanol. The mean specific activity was 976 dpm/ug.										
Remarks for Test Conditions	<p>Water and n-octanol were added to each test vessel. Each sample was then spiked with 10 ul of test material stock solution. Test conditions were as follows:</p> <p>20 mL distilled water and 1 mL of n-octanol (repeated) 20 mL distilled water and 2 mL of n-octanol 20 mL distilled water and 4 mL of n-octanol</p> <p>The test temperature was 21°C. Samples were shaken for five minutes and centrifuged for fifteen minutes at 4000 rpm to separate the phases. Each phase was sampled and the extract and stock solution were analyzed using liquid scintillation counting. Analytical data in units of radioactivity were converted to mass concentration units by using the specific activity of the test compound. The octanol/water ratio was calculated for each of three test conditions and expressed as a logarithm.</p>										
Results	<table><tr><th>Test Condition</th><th>Mean Log P_{ow}</th></tr><tr><td>20 mL distilled water and 1 mL of n-octanol</td><td>1.94 ± 0.27</td></tr><tr><td>20 mL distilled water and 1 mL of n-octanol</td><td>1.72 ± 0.15*</td></tr><tr><td>20 mL distilled water and 2 mL of n-octanol</td><td>2.94 ± 0.05</td></tr><tr><td>20 mL distilled water and 4 mL of n-octanol</td><td>2.77 ± 0.24</td></tr></table> <p>*Test condition repeat</p>	Test Condition	Mean Log P _{ow}	20 mL distilled water and 1 mL of n-octanol	1.94 ± 0.27	20 mL distilled water and 1 mL of n-octanol	1.72 ± 0.15*	20 mL distilled water and 2 mL of n-octanol	2.94 ± 0.05	20 mL distilled water and 4 mL of n-octanol	2.77 ± 0.24
Test Condition	Mean Log P _{ow}										
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20 mL distilled water and 2 mL of n-octanol	2.94 ± 0.05										
20 mL distilled water and 4 mL of n-octanol	2.77 ± 0.24										
Conclusion	The octanol/water partition coefficient of the test material was determined to range from 1.72 to 2.94 at 21°C under the stated test conditions.										

Data Quality	Reliable without restriction
References	Confidential business information
Other	November 27, 2002

2. Environmental Fate and Pathways

2.1 Biodegradation

Robust Summary 7-Biodeg-1

Test Substance	
CAS #	89347-09-1
Chemical Name	1,3,4-thiadiazole, 2,5-bis(tert-nonyldithio)
Purity	80 %–90% 1,3,4-thiadiazole, 2,5-bis(tert-nonyldithio) 10%-20% 2-Mercapto-5-tert-nonyldithio-1,3,4-thiadiazole.
Method	
Method/Guideline Followed	OECD 301C, Ready Biodegradability, Modified MITI Test
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (study performed)	1989
Contact time (units)	28 days
Preparation of Activated Sludge	Sludge was sampled from 10 sites including 5 sewage treatment plants and 5 sites from rivers, lakes and the sea. The filtrate of the supernatant of an activated sludge in actual use was mixed with an equal volume of the filtrate of the supernatant of the newly collected sludge and the mixture was cultivated at pH 6-8 under sufficient aeration. Thirty minutes after ceasing the aeration of the sludge mixture, supernatant equal to 1/3 of the total volume was removed. An equal volume of 0.1% synthetic sewage was added to the remaining portion and the mixture was aerated again. This procedure was repeated once daily. Culturing was carried out at 25±°C.
Mineral Medium	Prepared as outlined in the OECD guideline.
Preparation of Test Solution Cultures	Culture 1: 300 mL purified water and 30 mg of test material (abiotic control) Cultures 2, 3, 4: 300 mL mineral medium and 30 mg of test material Culture 5: 300 mL mineral medium and 30 mg of aniline (positive control) Culture 6: 300 mL mineral medium (blank) 30 mg/L (suspended solids) of activated sludge was added to test cultures 2, 3 and 4. The test apparatus was then assembled ensuring that it was airtight; oxygen uptake was then measured under conditions of darkness. Carbon dioxide was absorbed with soda lime No. 1. Magnetic stirrers stirred solutions. Oxygen uptake was recorded from all cultures continuously for 28 days.
Temperature of incubation:	24-26 °C

Analytical method:	Analysis of test substance by high performance liquid chromatography (HPLC). Measurement of biochemical oxygen demand (BOD) by closed system oxygen consumption measuring apparatus.
Study termination:	At 28 days, the pH of the content of each test culture and the concentration (HPLC) of the test material were determined.
Method of calculating biodegradation values:	<p>Degree of degradation (%) (BOD) = [(biochemical oxygen demand of sludge plus test material) - (biochemical oxygen demand of control blank)] / (theoretical oxygen demand required when the test substance is completely oxidized) x 100</p> <p>Degree of degradation (%) (HPLC) = (Amount of residual test material in water) – (Amount of residual test material in sludge) / (Amount of residual test material in water) x 100</p>
<u>Results</u>	The mean biodegradation of the test substance was 2% by the BOD method and 5% by HPLC determination at 28 days. The degree of degradation of aniline (positive control) calculated by the BOD method was 74% at day 7 and 80% at day 14. The test material was not considered biodegradable under the study conditions.
<u>Conclusions</u>	The test substance was not readily biodegradable.
<u>Data Quality</u>	(1) Reliable without restriction
<u>References</u>	Confidential business information
<u>Other</u>	Updated: 11/27/2002

3. Ecotoxicity

AQUATIC ORGANISMS

3.1 Acute Toxicity to Fish

Robust Summary 7-Fish Tox -1

<u>Test Substance</u>	
CAS #	89347-09-1
Chemical Name	1,3,4-thiadiazole, 2,5-bis(tert-nonyldithio)
Purity	80 %-90% 1,3,4-thiadiazole, 2,5-bis(tert-nonyldithio) 10%-20% 2-Mercapto-5-tert-nonyldithio-1,3,4-thiadiazole.
Method	
Method/Guideline followed	Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians, EPA-660/3-75-009, April 1975 p. 61.
Test Type	Acute Toxicity to Fish (Static Test Method)
GLP (Y/N)	Y
Year (Study Performed)	1985
Species/Strain	Fathead Minnows (Pimephales promelas)
Fish Number	10/concentration
Fish Size	Average length 24 mm; Average weight 0.2 g
Analytical Monitoring	No
Nominal Test Substance Concentration Levels	0 (control), 0 (solvent control), 100, 180, 320, 560 and 1000 mg/l
Test Concentration Preparation	Test solutions were prepared separately for each replicate test concentration by adding an appropriate aliquot (by weight) of test material directly to the test chambers. Prior to the addition of the test material 1.5 mL of dimethylformamide was added to each sample weight to increase dispersion of the test material in the dilution water. The solvent control also received 1.5 mL of dimethylformamide. The solutions were stirred vigorously prior to use.
Exposure Period	96 hours
Exposure Conditions	Static test conditions.
Vehicle	None
Statistical Analysis	None required based on the results.
Dose Rangefinding Study	Yes
Test Chambers	5-liter glass aquaria containing 15 liters of test solution
Diluent Water	Soft reconstituted water
Diluent Water Chemistry	Hardness 40-45 mg/l as CaCO ₃

	Alkalinity 30-35 mg/l as CaCO ₃ Conductivity 130 umhos/cm Dissolved Oxygen: 9.2 mg/L PH: 7.2-7.6
Photoperiod	16 hours of light, 8 hours of dark
Temperature Range	21-23 °C
Positive Control	Antimycin A
Remarks field for test conditions	All organisms were observed for mortality and the number of individuals exhibiting clinical signs of toxicity or abnormal behavior at 2, 24, 48, 72, and 96 hours after initiation of test material exposure. A separate group of fish was exposed to Antimycin A as a positive control.
<u>Results</u>	<p>After the preparation of the test material in the test chambers, an oily surface film and large yellow oily droplets were observed on the bottom of all test chambers. The amount of surface film and the size of the droplets increased with test material concentration. These observations were unchanged over the 96-hour duration of the study.</p> <p>No mortality or unusual observations were observed at any test concentration. The positive controls confirmed the LD50 of Antimycin A.</p> <p>Dissolved oxygen concentrations ranged from 7.1 to 9.5 mg/l during the study. These values represented 82-108% saturation at 23 and 22°C respectively, and were considered adequate for testing. The pH values ranged from 7.1 to 7.8.</p> <p>The 24, 48, 72 and 96-hour LC50s were each greater than 1000 mg/L (Nominal concentration). The 96 hour no observed effect level was 1000 mg/L.</p>
<u>Conclusions</u>	Under the conditions of this study the 24, 48, 72 and 96-hour LC50s were each greater than 1000 mg/L (Nominal concentration). The 96 hour no observed effect level was 1000 mg/L.
<u>Data Quality</u>	Reliable with restriction (Klimisch Code). Restriction due to the lack of analytical confirmation of exposure concentration and due to the presence of test material on the surface and at the bottom of each test chamber.
<u>References</u>	Unpublished confidential business information
<u>Other</u>	Updated: 11/13/2002

4. Toxicity

4.1 Acute Toxicity

4.1.1 Acute Oral Toxicity

Robust Summary 7-Acute Oral -1

<u>Test Substance</u>	
CAS #	CAS# 89347-09-1
Chemical Name	1,3,4-thiadiazole, 2,5-bis(tert-nonyldithio)
Purity	80 %-90% 1,3,4-thiadiazole, 2,5-bis(tert-nonyldithio) 10%-20% 2-Mercapto-5-tert-nonyldithio-1,3,4-thiadiazole.
Method	
Method/Guideline followed	OECD Guideline 401
Test Type	Acute oral toxicity
GLP (Y/N)	Not specified
Year (Study Performed)	1981
Species/Strain	Rats/Sprague-Dawley
Sex	Male/Female
No. of animals/dose	5/sex/group and 2/sex/group
Vehicle	Corn oil
Route of administration	Oral (intragastric)
Dose level	10,000 (5 /sex/group) and 5000 (2 /sex/group) mg/kg
Dose volume	15 mL/kg
Control group	No
Chemical analysis of dosing solution	No
Remarks field for test conditions	A single dose of the test material/vehicle mixture was administered intragastrically to fasted (18 hours) male and female rats at each dose level. A control group was not included. The animals were observed 1, 3 and 4 hours after dosing and at least once/day thereafter for 14 days. Individual weights were recorded on the day of dosing. All animals were euthanized, and gross necropsies were performed, at the conclusion of the observation period.
<u>Results</u>	LD50 > 10 g/kg (males and females)
Remarks	There were no deaths during the study. Decreased motor activity was observed in nine of ten high dose animals within 24 hours of test material administration at 10,000 mg/kg. Within this same time period diarrhea was observed in 2 of 5 high dose females and in 1 of 2

	low dose males. One male rat dosed at 10,000 mg/kg was observed to have a spleen with dark red edges. There were no other necropsy findings of note.
<u>Conclusions</u>	The test article, when administered to Sprague Dawley rats had an acute oral LD50 of > 10 g/kg.
<u>Data Quality</u>	Reliable with restriction (Klimisch Code). Restriction due to the lack of individual animal necropsy data in the final report.
<u>References</u>	Unpublished confidential business information
<u>Other</u>	Updated: 11/25/2002

4.1.2 Acute Inhalation Toxicity

Robust Summary 7-Acute Inhalation-1

<u>Test Substance</u>	
CAS #	CAS# 89347-09-1
Chemical Name	1,3,4-thiadiazole, 2,5-bis(tert-nonyldithio)
Purity	80 %-90% 1,3,4-thiadiazole, 2,5-bis(tert-nonyldithio) 10%-20% 2-Mercapto-5-tert-nonyldithio-1,3,4-thiadiazole.
Method	
Method/Guideline followed	OECD Guideline 403
Test Type	Acute Inhalation toxicity (Limit Test)
GLP (Y/N)	Not specified
Year (Study Performed)	1981
Species/Strain	Rats/Sprague-Dawley
Sex	Male and female
No. of animals/sex	5
Vehicle	None
Route of administration	Vapor inhalation (single 4 hour whole body exposure)
Dose level	2.75 mg/L (Nominal Concentration)
Vehicle control group	No
Chamber analysis	No
Remarks field for test conditions	<p>The above referenced guideline calls for the analytical confirmation of dose concentration. During this study the determination of chamber concentration was calculated as a nominal concentration based on test material usage and rate of airflow during exposure. The guideline also calls for an evaluation of animal body weights. Animals were weighed prior to exposure only.</p> <p>One group of five rats/sex was exposed for 4 hours to the test material as a vapor generated by bubbling dry air at 5/liters/minute through 1 liter of test material heated to 94°C. The vapor was delivered undiluted into a 37-liter Plexiglas exposure chamber. The nominal concentration of the test material in the atmosphere was 2.75 mg/L. Food and water were available ad libitum except during exposure. Animal observations for toxicological signs and mortality were recorded periodically during exposure and at least once daily during the 14-day observation period. Individual body weights were recorded on Day1 (immediately prior to exposure). Animals were sacrificed and subjected to a complete gross necropsy following the 14-day observation period.</p>
<u>Results</u>	LC50 > 2.75 mg/L nominal concentration
Remarks	All animals survived the exposure and observation periods. A clear nasal discharge, red encrustation around the nose and eyes and salivation were observed in four of ten animals during the exposure

	period. One male animal exhibited diarrhea immediately following exposure and on the following day. No other significant physical observations were recorded. Three animals had spongy lungs and/or brown foci through all lung lobes. Chamber oxygen concentration during exposure was 19.5%.
<u>Conclusions</u>	Following 4-hour whole body exposure to the test material vapor the LC50 in male and female Sprague Dawley rats was > 2.75 mg/L nominal concentration.
<u>Data Quality</u>	Reliable with restriction (Klimisch Code). Restriction due to the lack of analytical characterization of exposure concentration and due to the lack of individual animal necropsy data in the final report.
<u>References</u>	Unpublished confidential business information
<u>Other</u>	Updated: 11/25/2002

4.1.3 Acute Dermal Toxicity

<u>Test Substance</u>	
CAS #	CAS# 89347-09-1
Chemical Name	1,3,4-thiadiazole, 2,5-bis(tert-nonyldithio)
Purity	80 %-90% 1,3,4-thiadiazole, 2,5-bis(tert-nonyldithio) 10%-20% 2-Mercapto-5-tert-nonyldithio-1,3,4-thiadiazole.
Method	
Method/Guideline followed	OECD Guideline 402
Test Type	Acute dermal toxicity (Limit Test)
GLP (Y/N)	Not specified
Year (Study Performed)	1981
Species/Strain	Rabbits/New Zealand White
Sex	Male and female
No. of animals/sex/group	5
Vehicle	None
Route of administration	Dermal
Dose level	2 g/kg
Control group included	No
Remarks field for test conditions	<p>This study deviates from the above referenced guideline in that the dosing site was abraded prior to treatment. This was not considered a significant deviation from the guideline that would adversely affect the study results.</p> <p>Approximately 24 hours prior to topical application of the test material, the hair of each animal was closely clipped. Immediately prior to dosing the skin was abraded. A single dose of 2 g/kg of the undiluted test material was administered dermally to five male and five female animals. The test material was kept in contact with the skin for a period of 24 consecutive hours under a gauze pad and elastic film. The application site was washed clean of residual test material at the end of the 24-hour exposure period. The animals were observed for abnormal clinical signs daily for 14 days after treatment. Individual body weights were recorded on the day of dosing. Gross necropsies were performed on all animals on Day 14.</p>
<u>Results</u>	LD50 > 2.0 g/kg (males and females)
Remarks	No mortality was observed. One male rabbit had diarrhea on days 2, 3 and 4, as did one female rabbit on day 3. This female also exhibited this finding immediately prior to dosing. All animals were unremarkable from day 5 through study termination. No gross

	necropsy effects were evident.
<u>Conclusions</u>	The test article, when administered dermally as received to 5 male and 5 female New Zealand white rabbits had an acute dermal LD50 of greater than 2.0 g/kg.
<u>Data Quality</u>	Reliable with restriction (Klimisch Code). Restriction due to the lack of individual animal necropsy data in the final report.
<u>References</u>	Unpublished confidential business information
<u>Other</u>	Updated: 11/25/2002

4.2 Genetic Toxicity:

Robust Summary 7-Gentox-1

<u>Test Substance</u>	
CAS #	CAS# 89347-09-1
Chemical Name	1,3,4-thiadiazole, 2,5-bis(tert-nonyldithio)
Purity	80 %-90% 1,3,4-thiadiazole, 2,5-bis(tert-nonyldithio) 10%-20% 2-Mercapto-5-tert-nonyldithio-1,3,4-thiadiazole.
Method	
Method/Guideline followed	OECD Guideline 473
Test Type	<i>In Vitro</i> Chromosomal Aberration Assay in CHO Cells
GLP (Y/N)	Y
Year (Study Performed)	1989
Test System	Chinese hamster V79 Cells
Culture Preparation and Maintenance	Cells were thawed and cultured at 37°C, in 4.5% CO ₂ in air in plastic flasks. Seeding is performed at 5 x 10 ⁵ cells/flask in 15 mL MEM medium containing 10% fetal bovine serum.
Exposure Method	Dilution
Test Substance Doses/concentration levels	50 uL samples of concentrations of 1.0, 10, 20 ug/mL were evaluated with and without metabolic activation.
Metabolic Activation	With and without S9 fraction mix of livers of Aroclor 1254 pretreated Wistar rats.
Vehicle	Ethanol (final concentration did not exceed 1% v/v).
Positive Control concentration levels by activation status	Ethylmethanesulfonate, 0.72 mg/mL without activation Cyclophosphamide, 1.4 ug/mL with activation
Statistical Analysis	Statistical analysis of the data was not performed. Test data were consistent with control data.
Test Substance Solubility	Test substance solubility in the vehicle was determined.
Dose rangefinding study	Test substance and vehicle control tested in duplicate cultures each with and without activation. Test substance tested at concentrations of 0.05, 0.1, 0.5, 1.0, 5.0, 10, 15, 20 ug/ml without activation. Test substance tested at concentrations of 0.5, 1.0, 5.0, 10, 15, 20 ug/ml with activation. Cytotoxicity and mitotic indices were evaluated.
Remarks field for test conditions	A pretest dose range finding study was conducted at concentrations up to 20 ug/mL with and without metabolic activation. In the main study there were two treatment sets for each concentration of test substance, with (+S9) and without (-S9) metabolic activation. Cyclophosphamide (positive control) was tested with activation and ethylmethanesulfonate (positive control) was tested without activation. Prepared cultures were treated with test substance or control material and were incubated for 24 hours at 37°C, in 4.5% CO ₂ in air. Twenty-one and one half hours after the start of treatment the spindle inhibitor,

	Colcemid, was added to each culture to obtain a final concentration of 0.2 ug/mL. 2.5 hours later two slides were prepared for each group using Giemsa stain. Two-slides/treatment group were evaluated. 200 metaphase cells (100 per culture) each containing 21-23 chromosomes per treatment group were scored. Chromosomes were counted for each cell. Chromosome aberrations, either chromosome or chromatid type were recorded. Gaps were excluded from the total aberration frequency. Mitotic index was determined. The percent of aberrant cells and the frequency of aberration (%) per treatment group were determined. In order for a test substance to be considered to have induced a positive response compared to vehicle control a statistically significant dose related increase in the number of aberrant cells or a significant and reproducible positive response for at least one of the test points were required.
<u>Results</u>	The test substance was not mutagenic in this assay with or without metabolic activation.
Remarks	<p>In the prestudy toxicity evaluation, colony-forming ability, in the absence and presence of metabolic activation, at the 20 ug/mL test substance concentration was clearly reduced. Precipitate was evident at the higher concentrations.</p> <p>In the main study the mitotic index was reduced after treatment with the highest dose level only in the absence of metabolic activation.</p> <p>The test substance did not increase the frequency of cells with aberrations at any dose level, with or without metabolic activation. The aberration rates of the treated cells (0.0-2.5%) were in the range of the control values (0.0-3.5%). The positive control group had a higher percentage of aberrant cells than the vehicle control group with and without activation.</p>
<u>Conclusions</u>	The test material was not genotoxic under the conditions of this study.
<u>Data Quality</u>	Reliable without restriction (Klimisch Code)
<u>References</u>	Unpublished confidential business information
<u>Other</u>	Updated: 11/26/2002

Robust Summary 7-Gentox-2

Test Substance	
CAS #	CAS# 89347-09-1
Chemical Name	1,3,4-thiadiazole, 2,5-bis(tert-nonyldithio)
Purity	80 %-90% 1,3,4-thiadiazole, 2,5-bis(tert-nonyldithio) 10%-20% 2-Mercapto-5-tert-nonyldithio-1,3,4-thiadiazole.
Method	
Method/Guideline followed	OECD Guideline 471
Test Type	Bacterial Reverse Mutation Assay
GLP (Y/N)	Y
Year (Study Performed)	1989
Test System	<i>Salmonella typhimurium</i> and <i>Escherichia Coli</i>
Strains Tested	<i>Salmonella typhimurium</i> tester strains TA98, TA100, TA1535, TA1537, TA1538 and <i>Escherichia Coli</i> tester strain WP2uvrA
Exposure Method	Plate incorporation
Test Substance Doses/concentration levels	Initial and Confirmatory assays: <i>Salmonella</i> + (S9): 0.0, 10, 100, 333.3, 1000, 5000 ug/plate <i>Salmonella</i> - (S9): 0.0, 10, 100, 333.3, 1000, 5000 ug/plate WP2uvrA + (S9): 0.0, 10, 100, 333.3, 1000, 5000 ug/plate WP2uvrA - (S9): 0.0, 10, 100, 333.3, 1000, 5000 ug/plate
Metabolic Activation	With and without (S9 fraction-liver from Aroclor 1254 treated rats)
Vehicle	Ethanol
Tester strain, activation status, Positive Controls and concentration level	TA98 +S9 2-aminoanthracene 10.0 ug/plate TA98 -S9 4-nitro-o-phenylene-diamine 50.0 ug/plate TA100 +S9 2-aminoanthracene 10.0 ug/plate TA100 -S9 sodium azide 10.0 ug/plate TA1535 +S9 2-aminoanthracene 10.0 ug/plate TA1535 -S9 sodium azide 10.0 ug/plate TA1537 +S9 2-aminoanthracene 10.0 ug/plate TA1537 -S9 4-nitro-o-phenylene-diamine 50.0 ug/plate TA1538 +S9 2-aminoanthracene 10.0 ug/plate TA1538 -S9 4-nitro-o-phenylene-diamine 50.0 ug/plate WP2uvrA +S9 2-aminoanthracene 10.0 ug/plate WP2uvrA -S9 methyl methane sulfonate 10.0 ug/plate
Vehicle Control	Ethanol
Dosing Solution Analysis	No
Statistical Analysis	Mean revertant colony count and standard deviation were determined for each dose point.
Dose Rangefinding Study	Conducted in triplicate using tester strains TA98, TA100 and WP2uvrA and doses of test material ranging from 1.0 to 5000.0 ug/plate, with and without metabolic activation. Cytotoxicity was evaluated.
S9 Optimization Study	No
Remarks field for test	In the main study there were two treatment sets for each tester strain,

conditions	<p>with (+S9) and without (-S9) metabolic activation. Each of the tester strains was dosed with five concentrations of test substance, vehicle controls, and a positive control. Three plates/dose group/strain/treatment set were evaluated. The results of the initial assay were confirmed in a second independent experiment. 100 ul of test material, positive control or vehicle control were added to each plate along with 100 ul of tester strain, S9 mix (if needed) or S9 buffer, and 2000ul of top agar. This was overlaid onto the surface of 20 ml minimal bottom agar in a petri dish. Plates were incubated for 72 hours at 37°C in the dark. The condition of the bacterial background lawn was evaluated for cytotoxicity and test article precipitate. An automatic colony counter was utilized. If precipitate was present then colonies were counted by hand.</p> <p>The test article was considered positive if either a significant dose related increase in the number of revertants or a significant and reproducible increase for at least one concentration was induced. A significant response was considered as follows: TA100 - 2x increase in number of revertants; TA1535, 1537, 1538, 98 - 3x increase in number of revertants. In addition a dose dependent increase in the number of revertants was regarded as an indication of possibly existing mutagenic potential regardless whether the highest dose induced the described enhancement factor or not.</p>
<u>Results</u>	The test substance was not genotoxic in this assay with or without metabolic activation.
Remarks	<p>As a result of the dose range finding study dose levels of 10.0 to 5000 ug/plate were selected for the mutagenic assays.</p> <p>The test material was not cytotoxic to any tester strain at up to the highest concentration tested with or without metabolic activation.</p> <p>No significant and reproducible dose dependent increases in revertant colony numbers were obtained in any strain evaluated with or without metabolic activation. The test material was not considered genotoxic to any tester strain with or without metabolic activation.</p> <p>The positive control for each respective test strain exhibited at least a 5-fold increase (with or without S9) over the mean value of the vehicle control for a given strain, confirming the expected positive control response.</p>
<u>Conclusions</u>	Under the conditions of this study, the test material was not mutagenic.
<u>Data Quality</u>	Reliable without restriction (Klimisch Code)
<u>References</u>	Unpublished confidential business information
<u>Other</u>	Updated: 11/26/2002

5.8